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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,853	01/15/2004	Patrick E. Guire	9896.141.3.1	8747

22859 7590 05/26/2006

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EXAMINER	
BOYKIN, TERRESSA M	

ART UNIT	PAPER NUMBER
1711	

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,853	GUIRE ET AL.	
	Examiner	Art Unit	
	Terressa M. Boykin	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 46* is/are rejected.

7)☒ Claim(s) *2-45,47-51* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Arguments

Applicant's arguments filed 3-22-06 have been fully considered and appreciated but they are not persuasive.

First, the Examiner would like to convey that she considers the amendments presented do infact place the application in better condition for allowance. However, the claims remain broadly set forth that the claim continues to be interpreted by the Examiner as anticipated by the references while remaining within the scope of the specification. In should be noted that in order to prosecute the case resourcefully and expediently while giving the applicants the best possible search, it is imperative and practical for the applicants to clarify how the coated medical device including one or more surfaces is arranged/incorporated/formed or structured therein. Without such clarity of structure, the art of record remains within the scope of the present claims and the applicant's arguments although understood and appreciated are moot on those basis.

* It would be beneficial and helpful for the applicants in order to expedite the prosecution of the case to be in position of allowability by using language from the specification or drawn directly from the examples of the specification that would clearly and further specify the claimed language without, of course, unfairly limiting applicants intended.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by USP 6468649 Zhong, Samuel P. (note priority date)

The reference provides an implantable medical device having a substrate with a hydrophilic coating composition to limit in vivo colonization of bacteria and fungi. The hydrophilic coating composition includes a hydrophilic polymer with a molecular weight in the range from about 100,000 to about 15 million selected from copolymers acrylic acid, methacrylic acid, isocrotonic acid and combinations thereof.

The reference more specifically discloses a substrate, e.g. medical device such as angioplasty balloon, with lubricous, hydrophilic coating includes coating the substrate with a first aqueous coating composition comprising an aqueous dispersion or emulsion of first polymer having organic acid functional groups and first polyfunctional crosslinking agent having functional groups capable of reacting with the organic acid groups, and drying the first coating composition to obtain a water-insoluble coating layer including functional groups reactive with organic acid groups; and contacting the dried coating layer with a second aqueous coating composition comprising an aqueous solution or dispersion of hydrophilic polymer having organic acid functional groups, second polymer having organic acid functional groups, and second polyfunctional crosslinking agent having functional groups capable of reacting with organic acid groups,

and drying to effect covalent bonding of hydrophilic polymer and second polymer to the first polymer through the first or second crosslinking agent to form a hydrophilic coating. The first and second polymers may be the same or different. The first and second crosslinking agents may be the same or different.

The above may be used for providing a substrate, e.g. medical device such as angioplasty balloon (claimed), catheter, or guide wire, with hydrophilic coating which becomes lubricous when contacted with aqueous fluid, thus, making it possible to coat devices which are sensitive to high processing temperature such as polyethylene terephthalate balloon catheter.

Claims 1 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by LaVan DA, McGuire T, Langer R. "Small-scale systems for in vivo drug delivery" Department of Mechanical Engineering, Yale University, New Haven, Connecticut 06520-8284, USA.

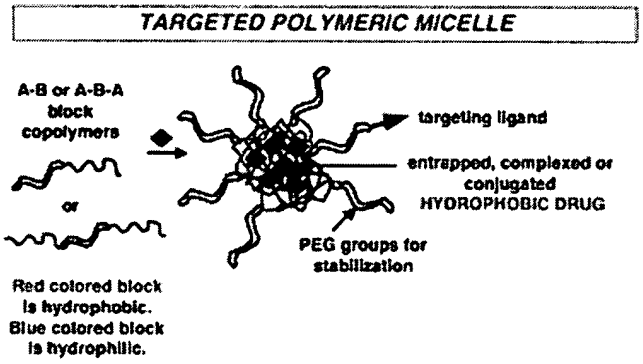
The article discusses developments of drug delivery systems which anticipate applicants broadly defined coated medical device.

"Recent developments in the application of micro- and nanosystems for drug administration include a diverse range of new materials and methods. New approaches include the on-demand activation of molecular interactions, novel diffusion-controlled delivery devices, nanostructured 'smart' surfaces and materials, and prospects for coupling drug delivery to sensors and implants. Micro- and nanotechnologies are enabling the design of novel methods such as radio-frequency addressing of individual molecules or the suppression of immune response to a release device. Current challenges include the need to balance the small scale of the devices with the quantities of drugs that are clinically necessary, the requirement for more stable sensor platforms, and the development of methods to evaluate these new materials and devices for safety and efficacy."

Claims 1 and 46 are rejected under 35 U.S.C. 102(e or b) as being anticipated by Noble et al. "Biomaterials Tutorial" Drug Delivery Systems; McAllister, D.V. , Allen, M.G. & Prausnitz, M.R. Microfabricated microneedles for gene and drug delivery. *Annu. Rev. Biomed. Eng.* 2,

289–313 (2000) see abstract; Santini, J.T. Jr. , Cima, M.J. & Langer, R. A controlled-release microchip. *Nature* 397, 335–338 (1999) see abstract.

The reference discloses the use of *polymeric micelles* which are used found to be effective in delivering hydrophobic molecules. When amphiphilic block co-polymers (i.e. have hydrophilic and hydrophobic segments) are placed in an aqueous environment, the large solubility difference between the hydrophilic and hydrophobic segments drives the formation of polymeric micelles. The hydrophobic segments form an inner core, where hydrophobic drugs can be loaded, while the hydrophilic segments (ex. Poly(ethylene glycol)) surround the core to stabilize and increase the solubility of the device [4]. Polymeric micelles are currently used in the delivery of tumor-targeting drugs, like Doxorubicin.



The abstract of McAllister, D.V. discloses that by incorporating techniques

adapted from the microelectronics industry, the field of micro fabrication has allowed the creation of microneedles, which have the potential to improve existing biological-laboratory and medical devices and to enable novel devices for gene and drug delivery. Dense arrays of microneedles have been used to deliver DNA into cells. Many cells are treated at once, which is much more efficient than current microinjection techniques. Microneedles have also been used to deliver drugs into local regions of tissue. Microfabricated neural

probes have delivered drugs into neural tissue while simultaneously stimulating and recording neuronal activity, and microneedles have been inserted into arterial vessel walls to deliver antirestenosis drugs. Finally, microhypodermic needles and microneedles for transdermal drug delivery have been developed to reduce needle insertion pain and tissue trauma and to provide controlled delivery across the skin. These needles have been shown to be robust enough to penetrate skin and dramatically increase skin permeability to macromolecules.

The abstract of Santini, J.T. Jr. discloses methods of achieving complex drug release patterns has focused on pulsatile release from polymeric materials in response to specific stimuli, such as electric or magnetic, fields, exposure to ultrasound, light or enzymes, and changes in pH or temperature. An alternative method for achieving pulsatile release involves using micro fabrication technology to develop active devices that incorporate micrometer-scale pumps, valves and flow channels to deliver liquid solutions. Here we report a solid-state silicon microchip that can provide controlled release of single or multiple chemical substances on demand. The release mechanism is based on the electrochemical dissolution of thin anode membranes covering microreservoirs filled with chemicals in solid, liquid or gel form. We have conducted proof-of-principle release studies with a prototype microchip using gold and saline solution as a model electrode material and release medium, and we have demonstrated controlled, pulsatile release of chemical substances with this device.

As previously noted above, applicants' claim 1 is so broad that it allows for the anticipation of the prior art as discussed in the specification, i.e. binding

methods, passivate biomolecule-compatible synthetic surface methods etc. Further, applicants claim is broad so as to read on drug delivery patches etc.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Please note that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Applicants may be referred to the Electronic Business Center (EBC) at http://www.uspto.gov/ebc/index.html or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Terressa Boykin whose telephone

number is 571 272-1069. The examiner can normally be reached on Monday through Friday from 6:30am to 3:00pm.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. The general information number for listings of personnel is **(571-272-1700).**

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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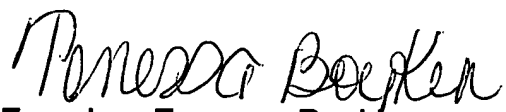

Examiner Terressa Boykin

TERRESSA M. BOYKIN
PRIMARY EXAMINER